



Bureau of TennCare Policy Manual

Policy No. :	HIP 06-018
Subject:	Use of Enrollee Records in Research
Date:	September 1, 2006
Approved by:	<i>Darin J. Gandy</i> 5/1/06 Date: 9/1/06

PURPOSE OF POLICY

This policy addresses how the Bureau of TennCare (the Bureau) will permit the use of Enrollee protected health information (PHI) for Research as required by The Health Insurance Portability and Accountability Act of 1996 (HIPAA) and other Bureau policies, federal or state regulations.

POLICY

The Bureau will provide access to Enrollee protected health information (PHI) in strict compliance with HIPAA rules under which the use of PHI is necessary for research purposes. The Bureau will provide enrollees with all the privacy rights granted by HIPAA and by federal and state laws and regulations.

DISCUSSION & LEGAL BASIS

The Bureau may use or disclose protected health information for research, regardless of the source of funding of the research, in keeping with the statutory provisions of HIPAA and other Bureau policies, federal or state regulations.

PROCEDURE

1. The TennCare Privacy Officer is responsible for obtaining documentation from the proposed researcher regarding an alteration to or waiver, in whole or in part, of the enrollee authorization required by HIP 06-_____ for use or disclosure of PHI;

2. The TennCare Privacy Officer shall ensure all documentation is complete and shall maintain such documentation within the TennCare Privacy Office for the time periods required under HIPAA.
3. The Research Privacy Board:
 - a. shall consist of the TennCare Privacy Officer as an *ex officio* member, the Bureau Chief Medical Officer as chair, and members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the enrollee's privacy rights and related interests;
 - b. shall include at least one member who is not affiliated with the Bureau, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any of such entities; and
 - c. does not have any member participating in a review of any project in which the member has a conflict of interest.

In the alternative of a privacy board, an Institutional Review Board (IRB) may be established in accordance with applicable regulations.

4. The Bureau must obtain from the researcher representations relative to the PHI sought that:
 - a. Use or disclosure is solely to review PHI to prepare a research protocol;
 - b. PHI shall not be removed from the Bureau by the researcher in the course of the review; and
 - c. The use or access is necessary for the research purposes.
5. For research of a decedent enrollee's information, the Bureau must obtain from the researcher representations relative to the PHI sought that:
 - a. Use or disclosure is solely for research on PHI of decedents;
 - b. Documentation, at the Bureau's request, of the death of such enrollees; and
 - c. The use or access is necessary for the research purposes.
6. For a use or disclosure to be permitted based on documentation of approval of an alteration or waiver, the documentation must include all of the following:

- a. Statement identifying the privacy board and the date on which the alteration or waiver of authorization was approved;
- b. Statement that the privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the statutory criteria;
- c. Brief description of the PHI for which use or access has been determined to be necessary by the privacy board;
- d. Statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures according to the Common rule, including normal review procedures;
- e. A privacy board must review the proposed research at convened meetings at which a majority of the privacy board members are present, including at least one member who satisfies the specific criteria of this policy, and the alteration or waiver of authorization must be approved by the majority of the privacy board members present at the meeting, unless the privacy board elects to use an expedited review procedure;
- f. A privacy board may use an expedited review procedure if the research involves no more than minimal risk to the privacy of the enrollees who are the subject of the protected health information for which use or disclosure is being sought. If the privacy board elects to use an expedited review procedure, the review and approval of the alteration or waiver of authorization may be carried out by the chair of the privacy board, or by one or more members of the privacy board as designated by the chair; and
- g. Documentation of the alteration or waiver of authorization must be signed by the chair or other member, as designated by the chair, of the privacy board.

DEFINITIONS

Enrollee: means those currently enrolled in all categories of TennCare Medicaid and TennCare Standard, including an individual eligible for and enrolled in the TennCare Program or in any Tennessee federal Medicaid waiver program pursuant to Sections 1115 or 1915 of the Social Security Act; and, for purposes of the Bureau Privacy policies, the term may also be used to reference one who was previously an enrollee during a period for which there is a privacy request or compliance inquiry.

HIPAA: means Health Insurance Portability and Accountability Act of 1996, for which administrative simplification, privacy and security regulations are codified at 45 CFR §§ 160-164.

Protected Health Information (PHI): means medical or health information, including non-medical facts such as address or date of birth, which identify an individual.

OFFICE OF PRIMARY RESPONSIBILITY

TennCare Privacy Officer, Office of General Counsel
TennCare Chief Medical Officer

RELATED FORMS

Bureau of TennCare – Research Application

REFERENCES

CFR § 164.512